UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/159,172	09/23/98	ENNIS F	UMMC98-13

HM12/0912

DAVID E BROOKS
HAMILTON BROOK SMITH AND REYNOLDS
TWO MILITIA DRIVE
LEXINGTON MA 02173-4799

EXAMINER	
SAUNDERS,D	
ART UNIT	**PAPER NUMBER**
1644	9

DATE MAILED: 09/12/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
159,172	ENNIS et al
Examiner	**Group Art Unit**
SAUNDERS	1644

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

P ri d for Response

A SHORTENED STATUTORY PERIOD FOR RESPONSE IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a response be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for response specified above is less than thirty (30) days, a response within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for response is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to respond within the set or extended period for response will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☑ Responsive to communication(s) filed on 5/22/00.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle,* 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

☑ Claim(s) 1-9, 11-20 is/are pending in the application.

Of the above claim(s)____ is/are withdrawn from consideration.

☐ Claim(s)____ is/are allowed.

☑ Claim(s) 1-9, 11-20 is/are rejected.

☐ Claim(s)____ is/are objected to.

☐ Claim(s)____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number)____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received:____.

Attachment(s)

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 6

☐ Interview Summary, PTO-413

☒ Notice of References Cited, PTO-892

☐ Notice of Informal Patent Application, PTO-152

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Other____

Office Action Summary

The amendment filed on 5/22/00 has been entered. Claims 1-9 and 11-20 are pending and under examination.

Applicant's response in the amendment of 5/22/00 has over come all previously stated bases of rejection under 35 USC 112 and 103. Claim amendments are considered supported by specification pages 8 and 10-12. The following correction has been entered in the previous office action mailed 11/30/99: at page 6, line 3 "11-3, 5-9" has been replaced with --1-3, 5-9, 11-12, 14-15 and 18 are--.

The subsequent statement of the rejection makes it clear that all of these claims were intended to be listed in the rejections over Baier et al.

Upon reconsideration of the breadth of the claims, prior art is newly cited herein below. This rejection has thus been made non-final. ~~Claim 1 is~~ Claims 1-9 and 11-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wisdom (Ed.) (Peptide Antigens...) Alone or in view of Zegers et al (Immunological Recognition...)

Before a consideration of the reference teachings the examiner notes that the claims are of sufficient breadth to encompass the mere in vitro screening of a polypeptide antigen, for fragments thereof which comprise T-cell epitopes (e.g. as in claim 9). Hence the term "vaccine composition" in the instant claims is interpreted to mean merely any peptide fragment of an antigen that may or may not represent a T-cell epitope. There is nothing in the disclosure that defines a vaccine composition as requiring that anything more be in the composition.

Wisdom teaches how to identify T-Cell epitopes of a polypeptide antigen via the screening of synthetic peptide segments of the polypeptide. See especially table 1 at page 184 and text at pages 208-215. With regard to the claim steps note the following teachings of Wisdom.

(a) Wisdom teaches that the peptides must be presented to T-cells by antigen presenting cells (APCs). See page 182.

(b) The reference teaches that T-cell lines or clones may be used and that such must be used for epitope mapping with CD8+ T-cells. See especially Table 1 at page 184 and text at pages 212-213.

(c)Wisdom teaches detection of the T-cell response via T-cell proliferation (tritiated thymidine incorporation into DNA), lysis of target cells (via 51Cr release), or production of cytokines (e.g. IL-2). See particularly pages 212-213.

(d)While Wisdom teaches further steps, such as determining the minimum size of the eptitope in the peptides identified as containing epitopes (page 214), the instant claim language is open to include such steps by virtue of reciting "comprising". As argued in the previous action, it then would have been obvious, once the identified epitopes have been incorporated into a vaccine composition (e.g. with a carrier protein, adjuvant pharmaceutical diluent etc. As taught in chapter 4 to test these in vivo since such testing is conventional and would be required by the FDA.

Note that while chapter 7 of Wisdom, which has been cited herein above as teaching the methods for identifying T-cell epitope, does not specifically mention that the identified T-Cell epitope would be a potential vaccine, one of ordinary skill would have readily recognized such a potential use of the epitope. See Wisdom at page 3, fourth full paragraph and see chapter 4, especially at pages 106-112, the latter section teaches that a synthetic peptide vaccine must incorporate both B and T-cell epitopes (e.g. when one wishes to immunize such that neutralizing antibodies are produced), and that such epitopes must be identified (see page 107), second full paragraph). Hence one would have readily recognized that the epitope screening methods taught in chapter 7 would be a stage in the screening of potential vaccine compositions for their ability to stimulate a T-Cell prior to further assessment in vivo.

All dependent claims are rejected over the teachings of Wisdom. The method of dependent claims 2,13 and 16 using human T-cells would have been obvious, in order that one might screen for the epitope that would be recognized by the human host that one desired to immunize. The method of claims 3, 12 and 15 using human APCs, alone or with human T-cells would have been obvious since human T-cells recognize peptides in the context of self MHC, which would be human when human APCs are used. Further, in the case of claim 20 it would have been obvious to employ autologues APCs since T-cells best recognize foreign peptides in the context of self MHC which is of the same allotype as that of the host from which the T-cells have been obtained.

The limitations of CD4+ and CD8+ T-cells, as recited in claims 4, 5,7 and 19 are taught by Wisdom at page 212.

The sources of APCs recited in claim 6 are conventional and hence would have been obvious.

The response readouts recited in claims 7 and 8 have been noted supra as taught by Wisdom at pages 212-213.

It is considered that Wisdom's teaching are sufficient for a statement of obviousness. However, Zegers et al will be optionally relied upon for providing additional motivation for using functional assays (i.e.cell culturing assays with a readout of T-cell function such as proliferation) are the most preferred method for identifying T-cell epitopes when one desires to identify T-cell epitopes to be vaccines. See pages 106-108. Zegers et al teach that either synthetic peptides or proteolytic fragments (produced by Cathepsin D) may be used in such assays (page 108, col.) They teach that peptides fragments must be presented with the use of MHC on the surface of APCs (page 106-col. 1).

Any inquiry concerning this communication should be directed to D. Saunders at telephone number (703) 308-3976.

David A. Saunders

DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT 182/1644

Saunder/sg

8/28/00